



# SAFE THAI

Safety and Environmental Best Practices Exchange  
for Transportation of Hazardous Substances in the Industry

A Project Funded by the

European Union



(Under the Thailand - EC  
Cooperation Facility)

## Safety and Environmental Best Practices Exchange for Transportation of Hazardous Substances in the Industry

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A Project Implemented by



Hazardous Substances Logistics  
Association



adelphi research

# Agenda

- **Short Intro on Adelphi Research**
- REACH
- RoHS
- Discussion

**Adelphi Research** is a Berlin-based independent, non-profit institute that develops and implements innovative sustainable development strategies.

### **Adelphi Research...**

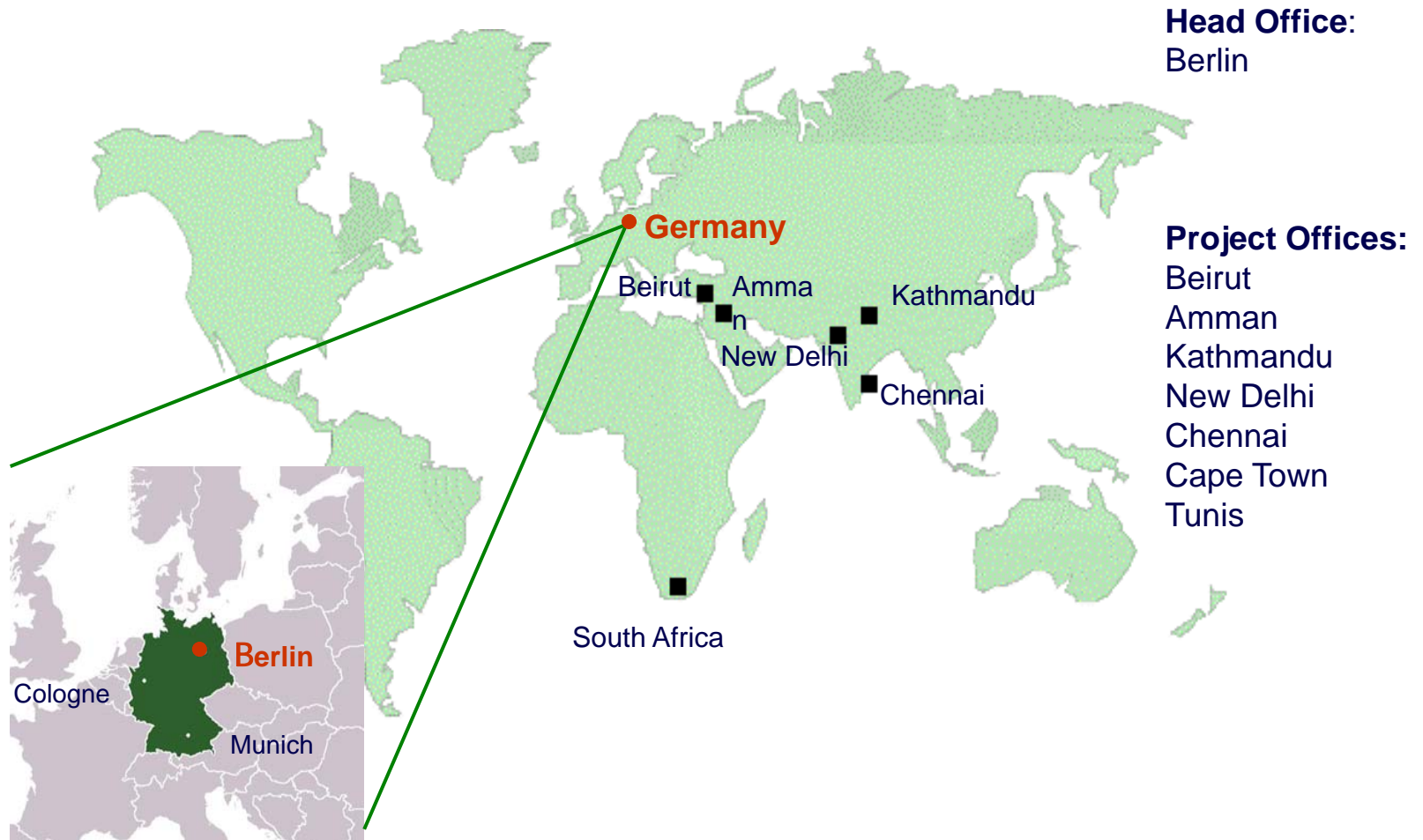
...increases awareness and understanding of political, economic and technological forces driving global change

...provides expert knowledge and advice to decision-makers at all levels of policy-making

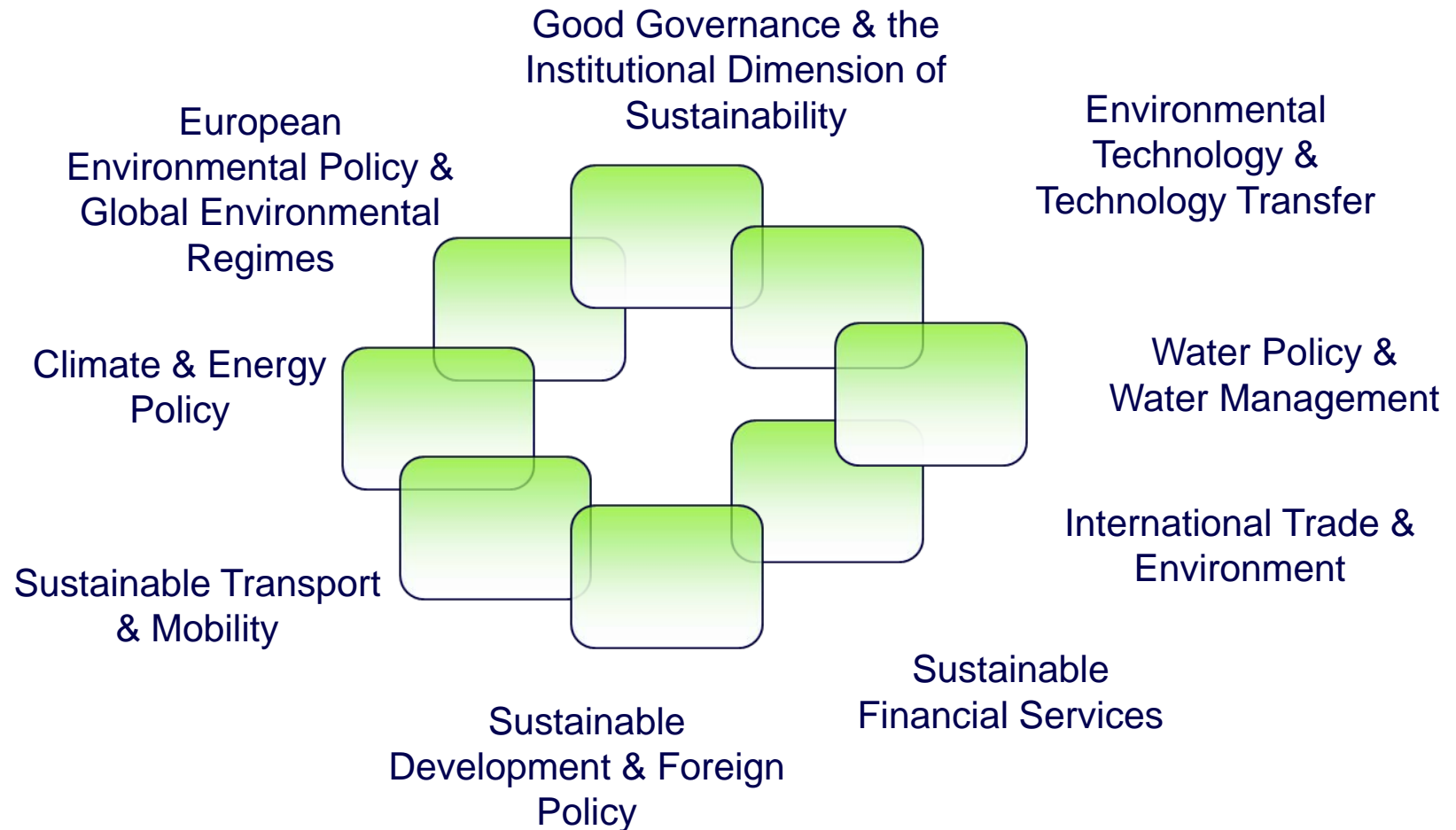
...conducts a broad range of applied research, analysis and public policy consulting

...manages complex projects accurately and reliably to fully meet all clients' requirements.

# Adelphi worldwide



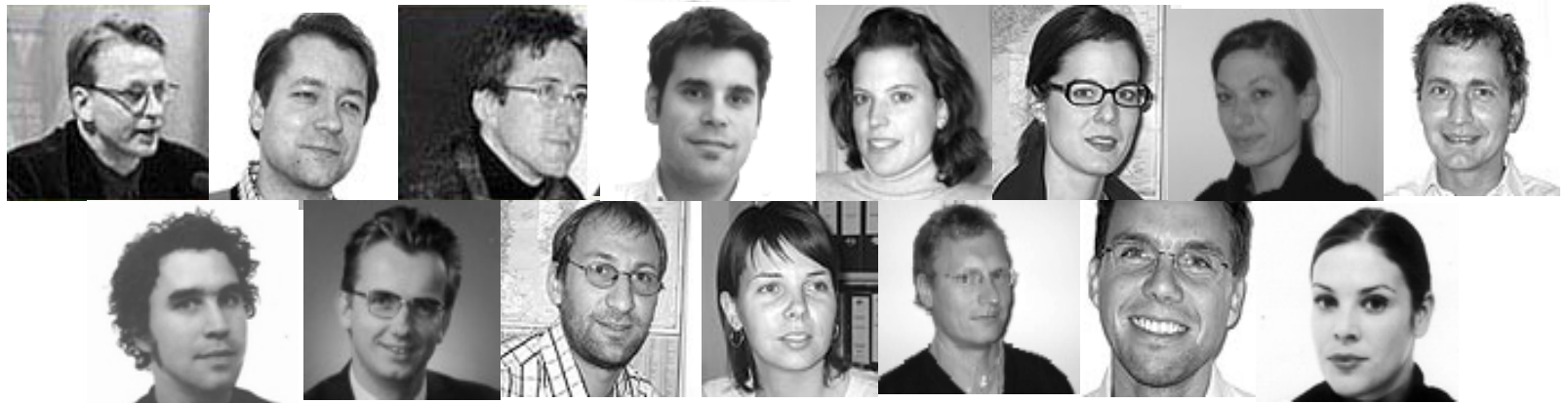
## Our Fields of Expertise:



# Team

**Adelphi Research** staff have worked extensively in business and public policy networks, served as members of national delegations to international negotiations, and closely cooperated with key decision makers in public administration around the world.

Our executives, senior fellows and research assistants:



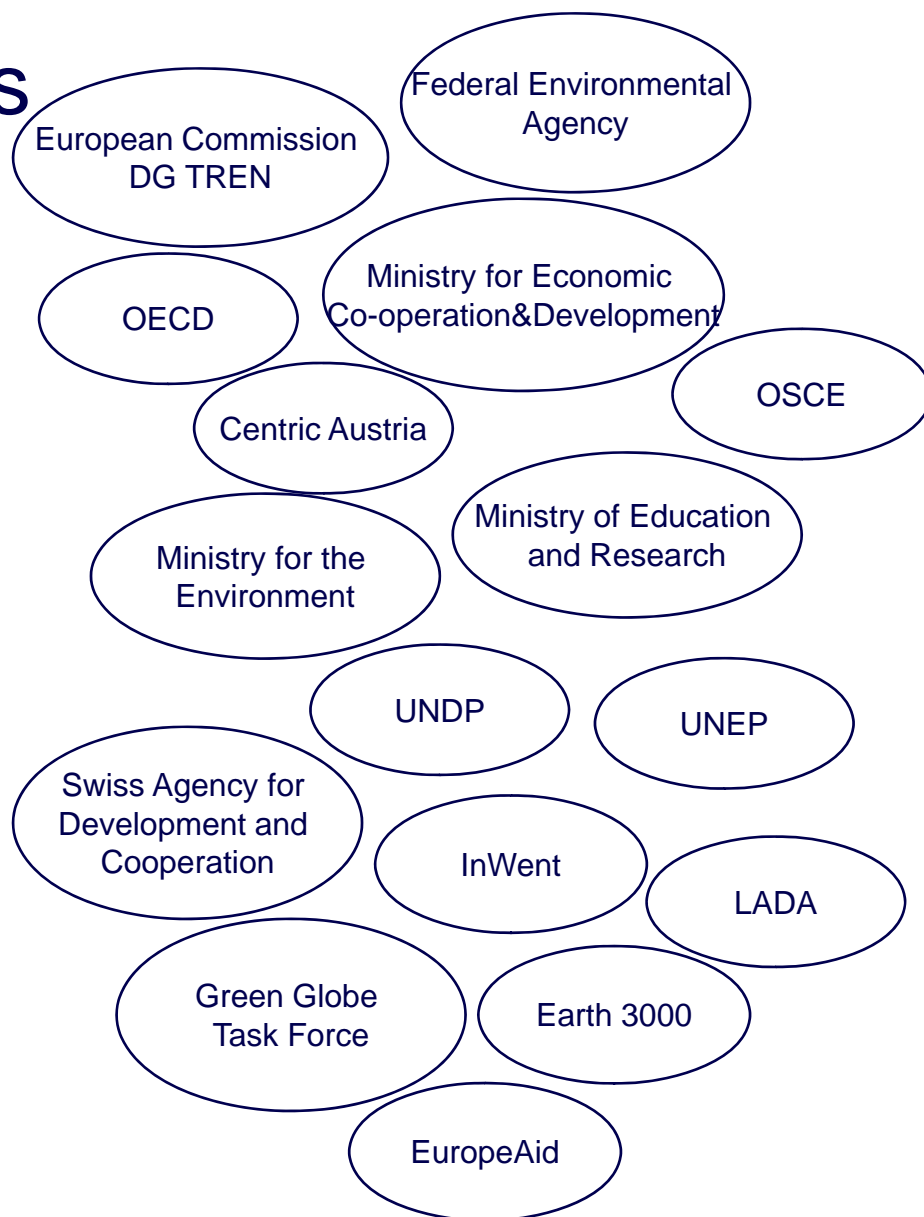
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# Agenda

- Short Intro on Adelphi Research
- **REACH**
- RoHS
- Discussion

# About REACH

REACH is a new European Community Regulation on chemicals and their safe use ([EC 1907/2006](#)). It deals with the **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemical substances. The new law entered into force on 1 June 2007.

REACH imposes different obligations for each role the sector performs: as a Downstream user of substances (e.g. magnesium) and preparations (e.g. engine oil), a Producer of articles (e.g. car, engine, bumper manufactured in the EU), or an Importer of articles/ preparations/ substances (from outside EU).

# Myths of REACH

- **REACH is a chemical industry issue**
- **REACH is an EU-based company issue**
- **REACH is an issue only for environmental, health and safety specialists**

# History of REACH

- ✓ The former EC legislative framework for chemical substances was a patchwork of many different Directives and Regulations which has developed historically.
- ✓ There were different rules for “existing” and “new” chemicals.
- ✓ However, this system did not produce sufficient information about the effects of the majority of existing chemicals on human health and the environment.

# History of REACH

The pre-REACH allocation of responsibilities was also not appropriate:

- ✓ Public authorities were responsible for undertaking risk assessments of substances rather than the enterprises that manufacture, import or use the substances; and these risk assessments were required to be comprehensive, rather than targeted and use-specific.
- ✓ Since 1993, only 141 high-volume chemicals were identified as priority substances for risk assessment. Recommendations for risk reduction were only available for a limited number of those chemicals.

# About REACH

- ✓ REACH is based on the idea that industry itself is best placed to ensure that the chemicals it manufactures and puts on the market in the EU do not adversely affect human health or the environment.
- ✓ This requires that industry has certain knowledge of the properties of its substances and manages potential risks.
- ✓ Authorities should focus their resources on ensuring industry are meeting their obligations and taking action on substances of very high concern or where there is a need for Community action.
- ✓ REACH creates a single system for both “existing” and “new” substances.

# Realities of REACH

- ✓ Companies that do not comply with REACH will have no market. REACH poses a threat to any company doing business in the EU (and businesses with customers or suppliers who do business in the EU).
- ✓ Business continuity can be adversely impacted by REACH and supply chains can be disrupted.
- ✓ Companies that understand the business implications and impacts of REACH and develop strategic action plans will gain competitive edge over those that do not.
- ✓ Substitutions need to be phased-in with product development programmes to minimize cost.

# Effects of REACH

**The following holds since the entry into force of REACH:**

**“no data - no market - no production”**

**This means that a substance that a company uses in a quantity of more than 1 tonne per year cannot be produced or imported, insofar as the substance is not registered.**

# Objectives of REACH

**REACH** aims to ensure a “high level of protection of promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation” (Article 1.1 **REACH**).

The **main objectives** of **REACH** are therefore:

- To reduce the risk from chemicals to humans and the environment and to reduce animal testing
- To encourage substitution of unsafe substances
- To require authorization for use or restriction of substances of very high concern (SVHC)

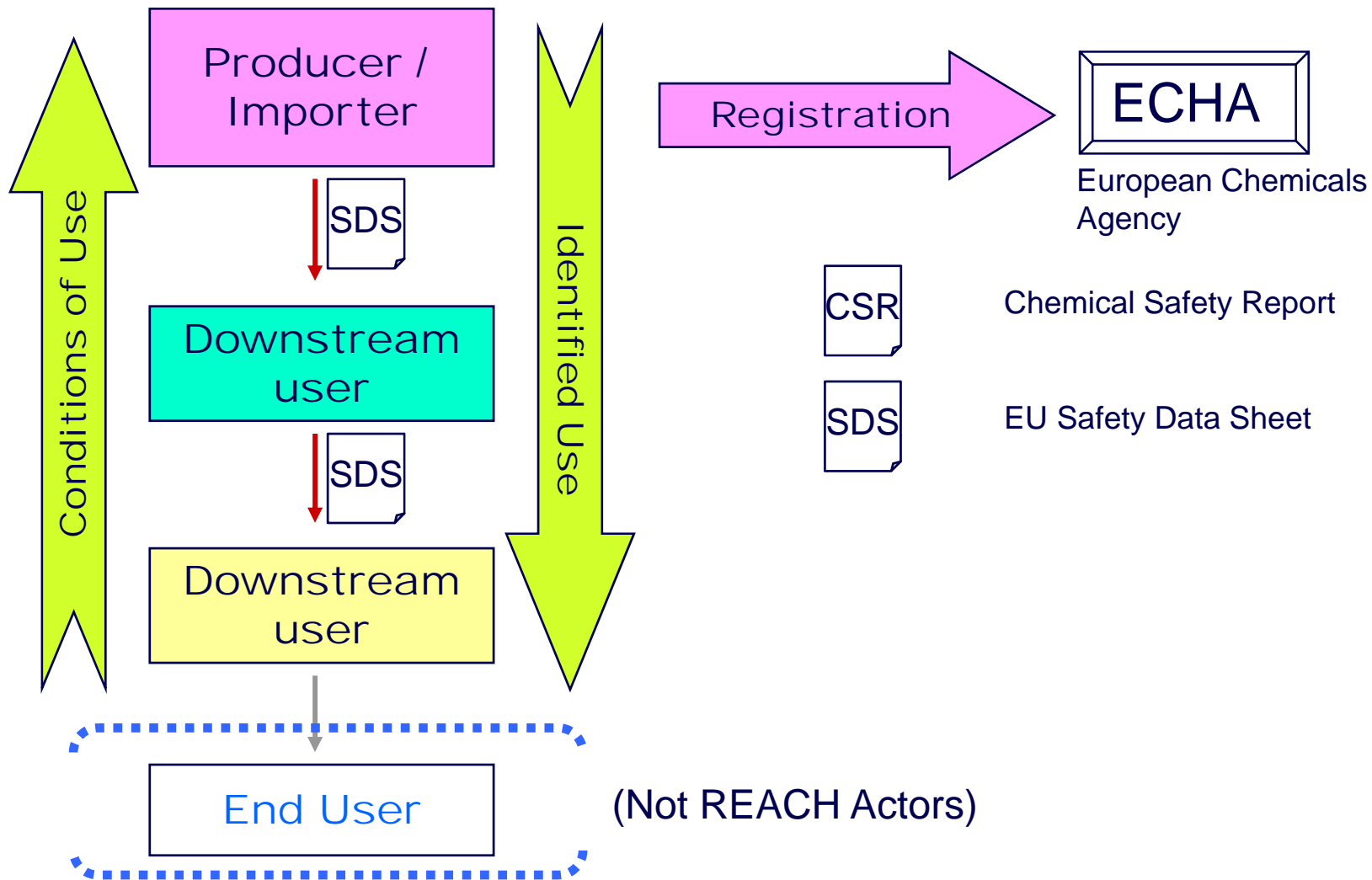
## Key Messages of REACH (1)

- ✓ **All substances are covered by the REACH Regulation unless they are explicitly exempted from its scope.**
- ✓ **Registration requires manufacturers and importers of chemicals to obtain relevant information on their substances and to use that data to manage them safely.**
- ✓ **To reduce testing on vertebrate animals, data sharing is required for studies on such animals.**
- ✓ **For other tests, data sharing is required on request by other registrants.**
- ✓ **Better information on hazards and risks and how to manage them safely will be passed down and up the supply chain.**
- ✓ **Downstream users are brought into the system.**

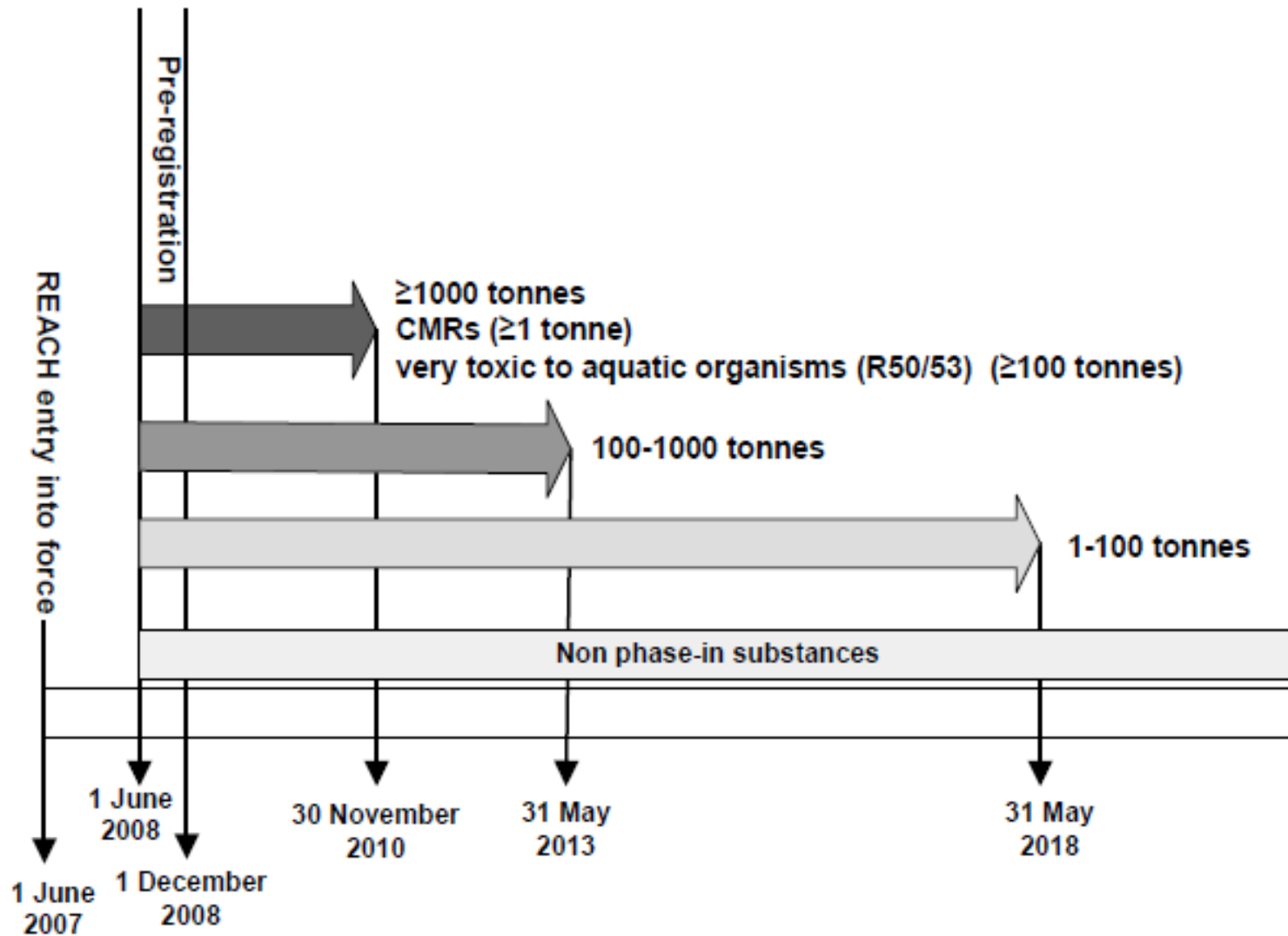
## Key Messages of REACH (2)

- ✓ **Substances with properties of very high concern will be made subject to authorisation; the Agency will publish a list containing such candidate substances.**
- ✓ **Applicants will have to demonstrate that risks associated with uses of these substances are adequately controlled or that the socio-economic benefits of their use outweigh the risks.**
- ✓ **The restrictions provide a procedure to regulate that the manufacture, placing on the market or use of certain dangerous substances shall be either subject to conditions or prohibited.**
- ✓ **The European Chemicals Agency (ECHA) will manage the technical, scientific and administrative aspects of the REACH system at Community level.**

# REACH in the Supply Chain



# REACH Time Schedule



# Waste REACH Context

- ✓ **REACH applies to recovered waste once it ceases to be waste;**
- ✓ **Recovery businesses are considered to be manufacturers under REACH, so may have registration obligations, unless certain exemptions apply;**
- ✓ **Where any recovered substances qualify as “phase-in” substances (e.g. they are listed in EINECS), they are eligible for the phased registration deadlines available in REACH.**
- ✓ **Exemptions for compost, biogas and anaerobic condensate are under Annex V.**
- ✓ **The European Commission has published draft guidance on REACH and recovered waste substances.**

# Implications for Businesses outside EU?

**In the first step it is important to clarify whether the product under discussion is an**

**Article**

**or a**

**Preparation**

# Definition of Article

According to REACH (Article 3)

“An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition”

Examples:

**Tools, Furniture, Motor Vehicles and Parts, Textiles and Leather Products, Computers, Electronics, Toys, ...**

# Definition of Preparation

According to REACH (Article 3)

“A mixture or solution composed of two or more substances”

Examples:

Varnishes, Dyes, Glues, Detergents, Lubricants, Alloys,  
like for instance Steel, ...

What needs to be registered?

**Not the Articles or the Preparations are subject to the registration requirement, but the therein contained**

## **Substances**

**Each Substance which is produced by a producer in the EU or physically introduced into the customs territory by an importer in a yearly quantity of over one tonne (1t/a) is subject to the registration requirement**

# Definition of Substance

According to REACH (Article 3)

**“A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition”**

When is a Substance in an Article subject to the registration requirement?

**A Substance that is contained in an Article needs to be registered when *all* of the following conditions are met:**

- 1. the Substance is contained in the Articles of the producer or the importer in a quantity of more than 1 tonne per year *and***
- 2. the Substance has not yet been registered for the use in question**
- 3. the Substance is intended to be released under normal or reasonably foreseeable conditions of use.**

# General example of an Article

## Ballpoint Pen →

**Is an Article which is normally subject to the registration requirement, as the ink is released by regular use. The ink contained in the product is usually a Preparation. There is no registration requirement if the Substances contained in the ink of the ballpoint pens are imported in quantities of less than a tonne per year each.**

When is a Preparation subject to the registration requirement?

**General Preparations are not themselves subject to the registration requirement, but the Substances contained in the Preparation *are***

**An importer of Preparations needs to register all of the Substances therein contained, but only insofar as the respective Substances pass the quantity threshold of one tonne per year**

# General examples of Preparations

## 1. Steel →

**Steel is an alloy from different Substances (metals), and in its raw form (e.g. coiled steel rolls) the single components need to be registered. However, when the steel is shaped into a specific part or a product, it becomes an Article and does not need to be registered**

## 2. Lubricants →

**Lubricants, for instance in the automotive industry, are usually made up out of many Substances. Lubricants are usually mixtures but these mixtures can also contain solutions (of oils), aside of additives and neutralising agents. Every Substance in the mixture needs to be registered, insofar as there is no *exemption* in accordance with Article 2 (7) (cf. Annex IV and V)**

# Duties of Producers / Importers



Producer /  
Importer of  
the Article



Customer

**Producers or importers of Articles have the duty to see:**

**Whether the Substances used in the Article will be released, and if yes, whether a registration requirement in accordance with Article 7(1) exists.**

**Whether Substances of very high concern are contained, and if yes, whether a notification following Article 7(2) is necessary**

**and the duty to inform their corporate customers (Downstream users) about the presence of these Substances and to give according directions for the safe use of the Article**

# EU customers → Downstream users

## Downstream user

A natural or legal person established in the EU who in the context of industrial or commercial activity uses a Substance as such or as contained in Preparations. Private end users are not Downstream users.

## Use according to REACH (Article 3)

“Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation”

# What Duties do Downstream Users have?

It is important to know the duties of EU customers!

Information duties since June 2007 → Meet the demands of Title IV “Information in the supply chain”

Safety Data Sheets → Passing on information in the context of the updating requirements (Article 31(9))

Are their information duties with regard to Substances, even if no Safety Data Sheet is required? If yes, pass on information to customers

Is there a duty to pass on information on Substances in Articles? If yes, pass on information to customers. Prepare information for customers on their request

Is there a duty to pass on information on Substances to suppliers? If yes, pass on information to suppliers.

# Communication: EU Safety Data Sheet



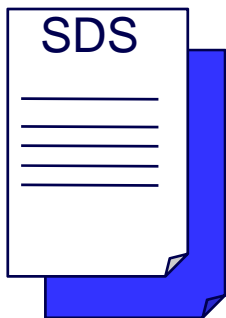
## Information transmission on Substances and Preparations

Possible dangers (classification and labelling)

Limit exposure (employees) and personal protective equipment (PPE)

Information on toxic and ecotoxic characteristics

Directions for disposal



## Expanded SDS under REACH Additionally

Threshold values with regard to health and environment for the specified use

Where appropriate in the Annex: Exposure scenarios related to the use

(from the CSR) with details on technical use conditions and risk management measures

# Late Pre-Registration

Pre-registration of Substances that were present and used in the EU under the pre-REACH regime would give a longer deadline for final registration in a **transitional regime**, but the deadline for pre-registration has **passed**.

**New entrants** (either new producers or new importers) can still apply for late pre-registration for “**phase-in**” Substances via the REACH-IT database, up to 6 months after they produce or import the Substance in quantities >1 tonne

([http://echa.europa.eu/reachit/portal\\_en.asp](http://echa.europa.eu/reachit/portal_en.asp))

## **Deadlines** for late pre-registration:

Substances produced or imported in quantities > 1000 tonnes: passed

Substances of very high concern in quantities > 1 tonne: passed

Substances very toxic to aquatic life (R50/53) in quantities >100 tonnes: passed

Substances in quantities >100 tonnes: **31st May 2012**

Substances in quantities > 1 tonne: **31st May 2017**

# Notification

## **Importers of Articles and Preparations have to notify Substances to ECHA for authorisation if:**

- These are substances of very high concern (for instance by being highly carcinogenic, mutagenic or toxic for reproduction)

### **and**

- These Substances are present in concentrations exceeding 0.1% and in total quantities of >1 tonne
- But not when the importer can rule out that humans or the environment can be exposed to the Substance

# Only Representative

Manufacturers of substances, formulators of preparations or, if the substances in their articles are required to be registered, producers of articles outside of the EU who export to the EU can nominate an **only representative** located within the EU to carry out required registration of the substance they export to EU.

The only representative will have to comply with all obligations of importers under the registration title of REACH.

In this case, all importers will be regarded as downstream users of the only representative. The only representative can represent one or several manufacturers, formulators or producers of articles outside of the EU and exporting to the EU.

## Summary (1)

### Does REACH affect companies outside the EU?

No - but your exports may be affected if you or your customers export :

- ▶ chemical substances (e.g. base chemicals, specialty chemicals, metals, natural substances if they are chemically modified)
- ▶ or mixtures (“preparations”) of chemical substances (e.g. cleaning products, formulated process chemicals, paints, motor oils)
- ▶ or substances or mixtures in containers (e.g. printer cartridges)
- ▶ or articles which contain substances which are intentionally released during their use (e.g. a fragrance in a scented eraser).
- ▶ or contain substances which are on a candidate list of “substances of very high concern”. ([http://echa.europa.eu/chem\\_data\\_en.asp](http://echa.europa.eu/chem_data_en.asp))

To any country in the EU or EEA

(Source: European Commission / ECHA: REACH Information for Exporters to Europe – What should my company know?)

## Summary (2)

### What should my company do?

**Create an inventory** of all substances or substances in mixtures or articles you export to the EU/EEA. Check if the substances or uses in your inventory are **exempted** from registration under REACH

**Identify** for each substance on its own or in a formulated product the **likely volume band per EU/EEA importer**:

If you export a chemical substance in your inventory to the EU/EEA > 1 tonne/year, ensure that your EU/EEA importer pre-registered it. If not, the EU/EEA importer or your Only Representative must register it. Only then you can start or resume exporting

**Consult the** website of the European Chemicals Agency for information on the Regulation and study the guidance on relevant REACH obligations

**Prepare information** for your EU/EEA importers or Only Representative

## Summary (3)

### What information is required for registration?

REACH sets different information requirements (e.g. on hazards, use conditions & exposure) for chemicals manufactured or imported in different volume bands.

The hazard information of a chemical substance must be shared among all registering companies in so-called SIEFs (Substance Information Exchange Forums).

If a company uses information owned by another company, the information owner is entitled to compensation.

New information must not be generated by testing on vertebrate animals without an agreement from the European Chemicals Agency.

(source: European Commission / ECHA: REACH Information for Exporters to Europe – What should my company know?)

# Further Information

The REACH section of the ECHA website has a good overview

The website also provides:

- ▶ A Navigator tool which will assist importers and Only Representatives to find out their obligations and how to fulfill them
- ▶ Extensive guidance on REACH provisions
- ▶ IT tools for REACH uses and help on how to operate them

For further information you can also contact

- ▶ Your importers
- ▶ The national helpdesk in the country of your importer or of your Only Representative

See the ECHA website: <http://echa.europa.eu>

(source: European Commission / ECHA: REACH Information for Exporters to Europe – What should my company know?)

## Case Stories (1)

### The example of a SME

Headquartered in Colmar in the East of France, this company produces microfilament technical textiles and has 50 employees.

- Implementing measures linked to REACH were initiated in January 2007.
- In April and May 2007, suppliers were contacted about REACH.
- A particular challenge was to get more safety and environmental information about the hazardous substances used in the factory.
- A timetable was created, starting with the opening of the pre-registration period of 1 June 2008.
- In addition to external help from the Strasbourg Chamber of Commerce, Evolon received support from the parent company which had appointed someone with specific responsibility to coordinate operations for REACH.

The company has found establishing a comprehensive inventory of all the substances that come into and go out of the premises very useful and recommends

this to other companies that will be affected by REACH.

## Case Stories (2)

### **Downstream user of chemicals sees REACH as an opportunity to further build consumer confidence**

With more than 30 manufacturing sites in the EU producing more than 200

Consumer branded products, this company will play a key role under REACH as a downstream user.

- More than 15 scientists have actively contributed to the preparation of guidelines
- Since 2005, a solid multifunctional REACH “Compliance Team” has been set-up. The company has created an inventory of its substances and is developing REACH compliance strategies.
- Their REACH requirement is a moving target as the company changes its composition of products, chemical use, tonnage, plants etc., on a regular basis. However several IT-tools have been developed to update the inventory of substances.
- They are also working in close collaboration with their suppliers to ensure that they will pre-register and register the substances they supply to them.
- They have pro-actively prepared exposure scenarios with industry associations.

## Case Stories (3)

### **Distributor of industrial chemical specialities, plastics, and basic chemicals**

This company is a leading Finnish distributor of industrial chemical specialities, plastics, and basic chemicals. It has 270 employees and operates in 9 countries.

- The Technical Trade Association has from the very start been organising training on REACH
- A REACH Task Force has been active in the company for two years.
- Training has been arranged.
- Suppliers both in and outside the European Union have been contacted.
- The data system has been upgraded to meet the requirements of REACH.
- The website contains a REACH section and customers have received a letter with information about REACH requirements.
- The Commercial Chamber of China and Russia have been informed about the impacts of REACH.

# RoHS Basics

- RoHS is a Directive on the Restriction of Hazardous Substances
- The Directive is complementary to the Waste from Electrical and Electronic Equipment Directive (WEEE)
- RoHS bans the use of certain hazardous substances in electrical and electronic equipment

# Banned Substances

**The following substances are banned for electrical and electronic equipment in the EU:**

- Lead
- Mercury
- Cadmium
- Hexavalent Chromium
- Polybrominated Biphenyls (PBBs)
- Polybrominated Biphenyl Ethers (PBDEs)

# Covered Sectors

The RoHS Directive applies to 8 of the 10 WEEE Categories:

1. Large household appliances
2. Small household appliances
3. IT and telecommunications equipment
4. Consumer equipment
5. Lighting equipment
6. Electrical and electronic tools (except large stationary industrial)
7. Toys, leisure and sport equipment
8. Medical devices (except implanted and infected products)
9. Monitoring and control instruments
10. Automatic dispensers

# Exempted Equipment

**In addition to categories 8 and 9, some products are exempted in Annex I of RoHS:**

- Compact fluorescent lamps with mercury up to 5 mg
- Fluorescent Lamps with mercury up to 5-10 mg (depending on type)
- Special purpose fluorescent lamps and non-fluorescent lamps with mercury
- Lead in glass of tubes
- Lead as an alloy in steel up to 0.35%, aluminium up to 0.4% and copper up to 4%
- Lead in several types of solders
- Lead in a range of other applications
- Cadmium plating except for applications banned by an earlier Directive, and cadmium alloys in loudspeakers
- Hexavalent chromium as an anti-corrosion aid in certain refrigerators

# Allowed Trace Amounts

- The RoHS Directive indirectly sets maximum concentration values for the banned substances in article 5(1 sub a) which is elaborated in Annex I
- Maximum concentration values relate to a 'homogeneous compound'. Examples would be metal alloys or plastics. Mechanically decomposable systems are not homogeneous.
- There is a 0.1% maximum value for lead, mercury, hexavalent chromium, PBBs and PBDEs
- There is a 0.01% maximum value for cadmium
- All values are by weight



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# Thanks Q&A

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